drug, cosmetic protection for canadians

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I.

INTRODUCTION

Few of the laws of this country touch every man, woman and child as intimately as does the Food and Drugs Act, for all must eat to live and be healthy and all at one time or another will need medicines to restore health impaired by disease or accident. For the protection of the individual, foods must be pure and wholesome and drugs must be as effective and reliable as modern science can provide. Canada's Food and Drugs Act is designed to give this protection as effectively as possible. It does this by outlawing the sale of foods and cosmetics that might cause harm to the person of the consumer, as well as fraud in the sale of foods, drugs, and medical devices, and also by requiring certain controls in the manufacture of drugs and in their sale and distribution.

A further safeguard is provided by the Proprietary or Patent Medicine Act, which controls manufacture, licensing,

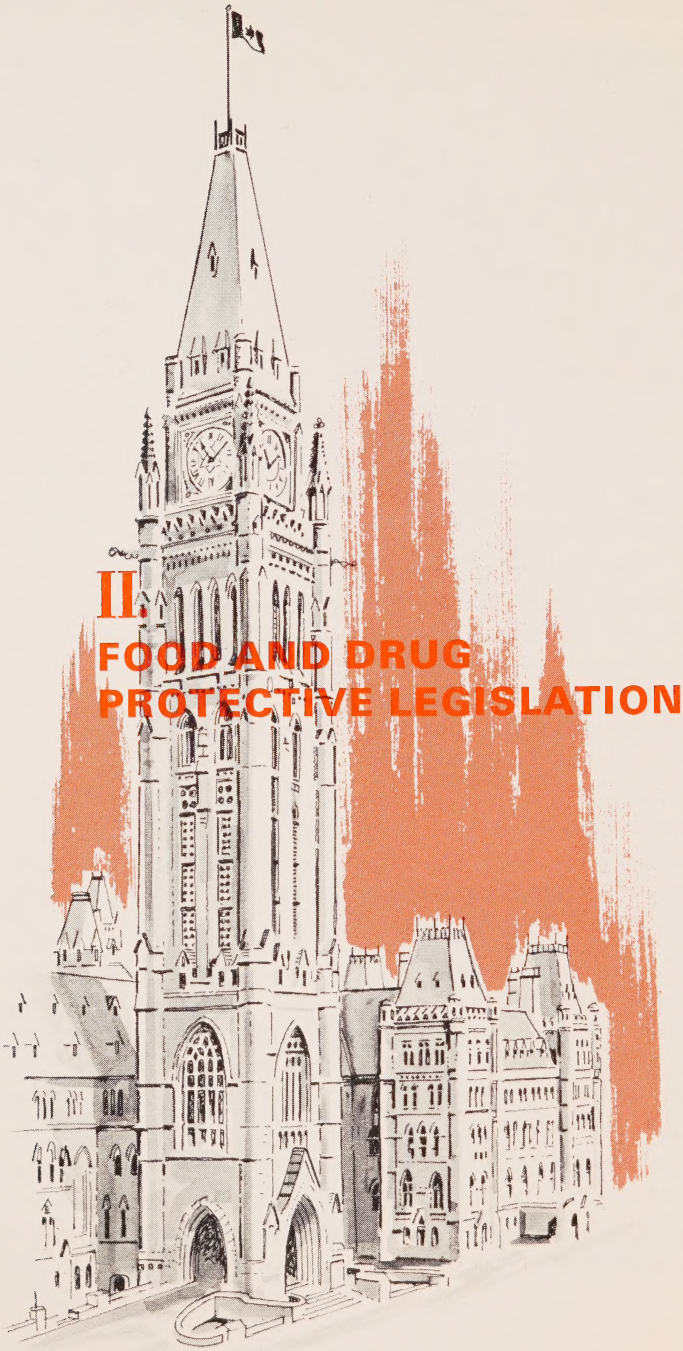
labelling, advertising and merchandising of home remedies. These medicines are often sold in retail outlets that are not drug stores.

The Food and Drug Directorate of the Department of National Health and Welfare administers these two acts and also the Narcotic Control Act. In carrying out its work, the directorate must enlist the co-operation of manufacturers, importers, distributors, retailers and members of the healing and merchandising professions, as well as that of agencies at all levels of government.

Consumers, too, must understand and support the aims and measures of this service and take an active part in ensuring the observance of the regulations so that Canadians may have full confidence in what they obtain at the grocery, drug store or beauty salon.

This booklet explains what the Food and Drug Directorate does and how it functions. It tells what we may expect of this service and what we, as consumers, should do when we have cause to complain about a food, drug or cosmetic. It also explains how complaints are investigated and how violations of the law are dealt with.

In addition to the services described here, testing of biologicals is performed for the directorate by the Laboratory of Hygiene of the Department of National Health and Welfare.

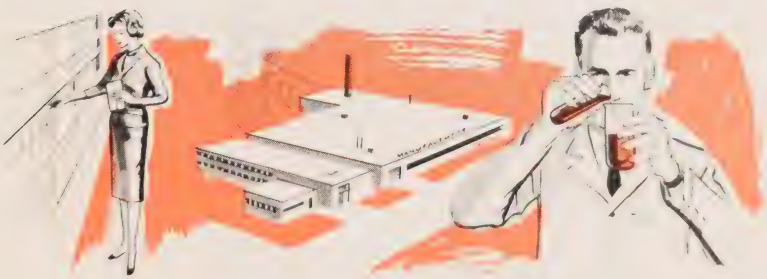


II.
FOOD AND DRUG PROTECTIVE LEGISLATION

1. THE FOOD AND DRUGS ACT

As is the case with most legislation, there are really two parts to the Food and Drug legislation, namely, the law itself and the regulations made by authority of the law. The law, which is an Act of Parliament, makes certain provisions in the area it covers, gives power to enforcement officers to do necessary things and provides penalties for violation of its provisions. The Act covers the general principles. The details are for the most part dealt with by regulations which take the form of Orders-in-Council. These regulations are just as binding as the Act itself and carry the same penalty for violations as does the Act.

Regulations are drafted by food and drug officials in the light of their experience and after consultation with consumers and the trade, reviewed by legal authorities, passed by the Cabinet and approved by His Excellency the Governor General, or by his Deputy.



Under the Act, it is possible to establish standards for foods, drugs, cosmetics and medical devices; to regulate packaging, labelling and advertising; to require certain controls in the manufacture of drugs and to control the distribution of drug samples and the sale of remedies for certain designated diseases; to stop clinical trials of new drugs or ban their sale; to specify drugs to be sold only on prescription and to make such other related provisions as may be considered necessary to prevent the consumer

or purchaser from being deceived or misled or to prevent injury to health.

The Food and Drug Regulations define actual standards of composition or identity. They also state, among other things, what information must appear on the label and where on the label some of this information must appear; what information is necessary to permit the evaluation of new drugs; what additives may be used in foods, and where, how and in what quantities they may be used. In addition, they establish a list of safe limits for residues of pesticides and weed killers that may appear on foods as a result of farm spraying programs.

Food and drug legislation in Canada has moved a long way since the first law to prevent adulteration of food was passed in 1875. Its full title was "An Act to Impose Licence Duties on Compounders of Spirits and to Amend the 'Act Respecting Inland Revenue' and to Prevent the Adulteration of Food, Drink and Drugs".

This so-called "Adulteration Act" was amended several times in the years to 1920, when it was repealed and replaced by the Food and Drugs Act. This in turn has undergone its share of revisions, to keep abreast of changing conditions. Among recent amendments to the act is a new part dealing with "Controlled Drugs". This was added in 1961 to combat the trafficking in "goof balls" containing habit-forming barbiturate and amphetamine drugs, while at the same time providing for the legitimate medical use of these drugs. The methods of control exercised are similar to those employed for the control of narcotics under the Narcotic Control Act. A further amendment, made in 1962, forbids the distribution of drug samples to the public, provides authority to prohibit the sale of a drug in the interests of public health and gives detailed powers to control the introduction of new drugs.

Regulations, too, are drafted, revised or repealed as circumstances dictate and this is a continuing activity of the Food and Drug Directorate.

2. THE PROPRIETARY OR PATENT MEDICINE ACT

The Proprietary or Patent Medicine Act is administered by the Bureau of Operations of the Food and Drug Directorate. The Act governs the manufacture and sale of remedies that are not defined in any publication of standard preparations.

This information is assessed by the directorate's medical officers and pharmacologists. If they are satisfied that the article meets the claims made for it and also meets all other requirements of the Act, it may then be registered. Formulas submitted for registration and which contain more than 2.5 per cent alcohol must be sufficiently medicated to make them unfit as alcoholic beverages. Formulas of this composition are submitted to an Advisory Board appointed by the Minister under a provision of the Act. This board comprises four members representing the medical and pharmacological professions.

The Advisory Board also advises the directorate on composition, drug dosages and regulatory management with respect to proprietary or patent medicines.

Continuing control over these registered preparations is provided by yearly renewal of licences and the attendant review of the preparations.

3. NARCOTIC CONTROL ACT

The Narcotic Control Act forbids traffic in narcotics or the possession, exportation, importation or cultivation of narcotics by persons other than those authorized under the Act or Regulations and provides severe penalties for violations.

The Act empowers the Governor in Council to make regulations (a) providing for the issue of licences for the importation, exportation, sale, manufacture, production or distribution of narcotics; (b) requiring specific label information, including the symbol "N" which must appear on all labels for narcotics or narcotic preparations; (c) authorizing the sale, possession of or other dealing in narcotics under certain prescribed conditions; (d) requiring the keeping of records by hospitals, physicians, dentists, veterinarians, pharmacists and other authorized persons who deal in narcotics, and, (e) prescribing penalties for breaches of the regulations.

The Narcotic Control Act and Regulations are administered by the Narcotic Control Division of the Food and Drug Directorate.

III.
ADMINISTRATION AND ORGANIZATION

The Food and Drug Directorate is a unit of the Department of National Health and Welfare. With the aid of a network of regional and district satellite offices, it administers and enforces food and drug laws throughout the length and breadth of Canada.

Because of recent rapid strides in the drug industry and the many advances in food technology, the directorate is confronted more and more with problems of increasing seriousness and complexity. To keep abreast of these developments the organization and facilities had to be strengthened and reinforced and the directorate's headquarters structure redesigned. New posts were created to relieve the Director of some of the responsibilities now grown too onerous and a clearer administrative line was adopted between field and enforcement work and that associated with research.

In his administration of the three food and drug laws, namely, the Food and Drugs Act, the Narcotic Control Act and the Proprietary or Patent Medicine Act, the Director-General, Food and Drugs, is assisted by the Deputy Director-General and advised, on policy matters regarding their respective fields, by the Assistant Director-General, Foods and Assistant Director-General, Drugs. In addition, a Drug

Advisory Committee counsels on drugs and an Advisory Board on proprietary or patent medicines.

The Food and Drug headquarters organization embraces a number of divisions, each with its own well-defined areas of activity set within the framework of the directorate's broader responsibilities. Thus there exists a specific service to deal in the particular with each situation or problem as it arises. When, as so often happens, the resources of several divisions are needed to resolve the matter at hand, they are geared to work smoothly toward realization of the common goal — the protection of the Canadian consumer.

While discharging their individual functions, the various divisions also serve in advisory capacities on matters involving their own specialization. In this way knowledge and experience acquired by individuals in their work and investigations is used to the fullest advantage at all times.

Inspection and enforcement are mainly carried out by the directorate's regional organizations. Five in number, they are situated in Vancouver, Winnipeg, Toronto, Montreal and Halifax. Each is equipped with laboratory services and an inspection service which staffs a number of district offices with field inspection personnel.

There are twenty-three such district offices located strategically from Newfoundland to Vancouver Island. The regional boundaries are defined for administrative purposes as follows:

The Western Region with headquarters at Vancouver extends from the Pacific Coast to the Saskatchewan border. Saskatchewan and Manitoba constitute the West Central Region whose headquarters are in Winnipeg. Ontario is covered by the Central Region administered from Toronto. The East Central Region with headquarters at Montreal covers Quebec Province and the Atlantic Provinces come under the Eastern Region administered from Halifax.

These regional food and drug staffs work closely with customs inspectors on the imports of foods, drugs and cosmetics. They check labels and regularly take samples for examination. Each district inspector is responsible for checking foods, drugs and cosmetics imported, manufactured or sold in the territory to which he is assigned, and he must travel many miles in the course of his duties.

* * *

On succeeding pages will be found a brief description of each of the various components that make up the Food and Drug Directorate's headquarters establishment.

1. CONSUMER DIVISION AND ADVISORY COUNCIL OF CONSUMERS

In the administration of laws enacted strictly for the protection of the consumer, it seemed reasonable to suppose that consumers' needs — as expressed by the consumers themselves — should receive careful consideration. While attention to consumer wants had long been one of the guiding principles of the directorate, one of the problems was how to collect and consolidate such information in a form that would reliably present the wishes of the main body of consumers. To this end, a Consumer Division was established within the directorate in 1957.

The Consumer Division acts as a link between the directorate and the consumer. On the one hand, the division explains to the consumer what the Food and Drugs Act is, how it is administered, and what it does and does not empower the directorate to do. On the other hand, the division seeks from the consumer any and all information that may be of guidance to the directorate in the administration and enforcement of the Act.

Informing the Consumer

The task of informing and educating the consumer takes many forms.

The Written Word: Articles are written for publication in consumer magazines and pamphlets and handouts are prepared on subjects of special interest to the public in the fields of foods, drugs and cosmetics.

The Spoken Word: Talks and lectures are given to gatherings of consumers, educators and other professional groups with an interest in consumer matters, and on radio and television.

The Picture: Large-scale displays for showing at exhibitions and similar functions and smaller-scale or poster type displays for more intimate gatherings portray graphically different facets of the directorate's work or focus attention on a current problem or undertaking. Use is made, too, of films, slides and photographs in telling the "Food and Drug" story.

Listening to the Consumer

The voice of the consumer can be, and indeed must be, an important consideration in the formulation of consumer legislation. Consumers are therefore encouraged, both as members of consumer organizations and as private individuals, to press for those things they sincerely feel will benefit all consumers. Often, a well-considered resolution submitted by an organized group will bring quick results. At other times, more specific evidence of consumer wants is required and this is best obtained through consumer opinion surveys which are prepared and conducted by the division in consultation with experts in the particular field. Survey results, which are made available to the public, often serve as a basis for introducing new or amending old legislation.

Consumer complaints, too, serve as a useful guide as they help to focus the attention of the directorate to

problem areas which may require special consideration. Consumers are therefore encouraged to report to the Consumer Division all apparent infractions of the Food and Drugs Act and Regulations, for the directorate's investigation. Such complaints are given individual attention and result in corrective action whenever and wherever it is required.

The main body of the Consumer Division is located in Ottawa, but in 1964 provision was made for Consumer Consultants, attached to the division but working in the regions, to help carry out the division's program and establish closer relationship with consumers in outlying areas.

Advisory Council of Consumers

In 1964 the Minister of National Health and Welfare announced the formation of an Advisory Council of Consumers to advise the department in matters involving consumer interest in the administration of the Food and Drugs Act and the Proprietary or Patent Medicine Act. This council works strictly within the confines of these two acts. It does not, for example, advise on textiles, household appliances or sports equipment; nor does it concern itself with prices, as none of these things are covered by the legislation mentioned in the council's terms of reference.

The membership of the council consists of a permanent chairman, a permanent secretary and 15 members appointed for a period of three years, and every effort is made to make the council representative of all areas of Canada. The members, as is to be expected, are selected from among persons whose work and interests have been largely in consumer fields, particularly suiting them to the task of obtaining and interpreting the consumer viewpoint and advising the department accordingly.

The council meets two to three times a year, or whenever special circumstances dictate.

2. RESEARCH LABORATORIES

Modern food and drug production is highly technical and represents the results of the vast research and development facilities of industry. Evaluation of the safety of foods and drugs requires the application of many scientific disciplines. It is essential therefore for the protection of the Canadian consumer that research be carried out continually on many aspects of foods and drugs, cosmetics and medical devices. This work is undertaken in the Research Laboratories of the Food and Drug Directorate.

The laboratories, which comprise five main divisions in addition to ancillary services, conduct a diversified program which covers composition, purity, mode of action, potency, effectiveness, safety, cleanliness, and such claims as may be verified by experimental means. This program includes, also, the development of new methods of testing and analysis, the study of information submitted about new drugs to ensure that they are safe and effective when used as directed, as well as the study of information on the safety of all additives used in or proposed for use in foods.

This work employs the skills of highly-trained professional staff who carry on active research projects in such diverse fields of specialization as pharmacology, chemistry, biology, toxicology, microbiology and nutrition. Food and Drug scientists meet and discuss scientific matters with other specialists in their own and allied fields, both at home and abroad, and their work is published in a wide variety

of scientific journals. It is essential that they keep abreast of the most recent developments in science that may have a bearing on their endeavours. The Research Laboratories also collaborate in an active way with numerous official bodies and organizations such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), and the Association of Official Agriculture Chemists (AOAC) and in committees of the British Pharmacopoeia, the U.S. Pharmacopoeia and the National Formulary. Staff members from time to time take temporary assignments with these organizations and with universities, while workers from many parts of the world come to the directorate for specialized training in food and drug analysis and investigation.

The work of the Research Laboratories is subdivided as follows:

Food Chemistry

This division develops methods for detecting in foods trace quantities of poisonous materials such as pesticide residues, toxic substances produced by moulds and other microorganisms, and chemicals which way be added intentionally as processing aids or which may find their way into foods unintentionally. It employs modern techniques and equipment to develop or improve methods for detection of adulteration and filth in foods and alcoholic beverages. The Food Chemistry Division also appraises the reliability of analytical methods in submissions from companies requesting permission to use new pesticides and food additives and it assists in the preparation of new standards for foods.

Microbiology

Microbiology Division carries out investigations to protect consumers from hazards of microbial contamination of foods. These hazards include food-borne infections of bacterial, fungal or viral origin; food poisoning due to microbial toxins, and food spoilage. The division examines new processes, new foods and new packaging methods and develops

and applies better ways of detecting dangerous bacteria and their toxins and of bringing these hazards under control in the food and drug industries. Its research helps the directorate to make sound decisions to prevent health problems with foods and to act with speed and effect when special problems do arise.

Investigations conducted by this laboratory have revealed that gamma irradiation can induce many mutational changes in bacteria and viruses. These changes may include the development of resistance to irradiation, modification of virulence, development of toxins at present unrecognized, and many others. Such effects are undergoing further study in order to estimate possible health hazards that might arise if these new processes were to be applied to foods without thorough investigation of their safety.

Nutrition

This division carries out extensive studies on the nutritional value of proteins, fats, minerals and vitamins in foods and pharmaceutical products. Special attention is paid to the development of methods to evaluate the validity of advertising claims. The division develops analytical methods for the estimation of amounts of vitamins in foods and pharmaceuticals and is also concerned that vitamins and other drugs in pharmaceutical preparations be readily available to the body (e.g., it is possible for an improperly manufactured tablet to pass completely through the body without releasing any of its medication). Studies are also made on the effects of food processing on the nutritive value of foods.

Phamaceutical Chemistry

The Pharmaceutical Chemistry Division develops physical and chemical methods of analysis for drugs and studies physical characteristics of pharmaceutical dosage forms. It also studies the release of drugs from medicinal formulations, and factors affecting the degradation and stability of drugs. In addition, the division reviews the chemical

aspects of new drug submissions; participates in collaborative studies with national and international agencies concerning the establishment of standards for the manufacture, processing and quality control of pharmaceuticals, and advises the directorate on technical problems. One section of the division is engaged in studies of opium, marihuana and related products which become involved in illicit traffic.

Pharmacology and Endocrinology

This division is concerned with research in the broad fields of pharmacology and endocrinology. The studies include acute and chronic toxicity of drugs, their therapeutic action, their storage, excretion and metabolism, and their biochemical, physiological and anatomical effects. The toxic effect of hormones, pesticides, cosmetics and food additives and other substances suspected of being adulterants in foods, drugs and cosmetics are also studied. Other important aspects of the work of the division are to devise or improve biological methods for testing hormones and other drugs for potency and to test medical devices.

Research Services

To permit the efficient functioning of the Research Laboratories, various specialized services and skills are necessary and required continually by each division. The research services operating under the Research Laboratories comprise the following sections:—

Pathology:— This section studies the effect of drugs, chemicals, cosmetics and other possibly harmful substances on the cells, organs and tissues of test animals, and develops new methods and techniques for this work. It is also concerned in maintaining and improving the health of test animals and studies factors that alter the response of the animals to test substances. An animal colony is maintained to supply test animals for use by the various scientific divisions.

Biometrics:— The Biometrics Section has two main functions. It is responsible for developing statistical techniques for sampling and examining foods and drugs on the market, and for the evaluation of experimental data obtained in the laboratory. It also evaluates laboratory and inspection programs.

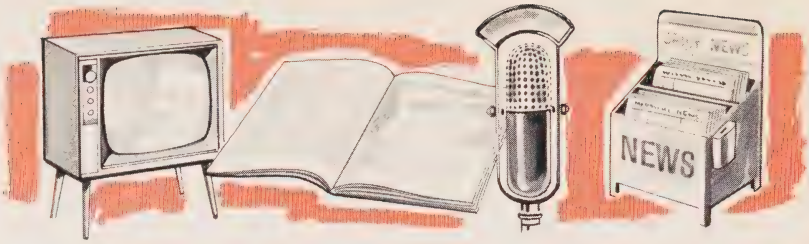
Instrumentation Section:— This section has in its care large complex instruments including X-ray diffraction equipment and radioactive counting instruments. It assists in the application of instrumental methods, such as X-ray diffraction, spectroscopy and radioactive tracer techniques, to the work of the directorate. It is also engaged in research on the determination of radioisotopes and poisonous metals in foods and drugs.

3. BUREAU OF OPERATIONS

The Bureau of Operations is responsible for the direction and co-ordination of the inspection, laboratory and administrative functions in the regions, and for inspection functions at headquarters.

The bureau consists of two main divisions. The first, the Field Program Division, assists the regions in carrying out and co-ordinating their programs of inspection and enforcement and supplies the necessary direction, supporting services and resources. It co-ordinates all demands placed on the regions by headquarters; reports upon the progress of the regulatory programs and acts as headquarters representative for the regions.

The second, or Advertising, Labelling and Registration Division, reviews all radio and television advertisements for the Board of Broadcast Governors as required by the Broadcasting Act; reviews national newspaper and magazine advertising for all products within the scope of the Food and Drug and Proprietary or Patent Medicine Acts, and discusses proposed advertisements with national advertisers



and their agencies or representatives. This division also looks after the registration and licensing of proprietary or patent medicines and of manufacturers as well as the review and annual licensing of injectable drugs, vaccines, sera and antibiotics; takes all necessary enforcement action with respect to products which do not meet the requirements of the Act and examines labels of foods, drugs, vitamins and cosmetics submitted to Ottawa by national manufacturers, by importers or by Food and Drug regional offices.

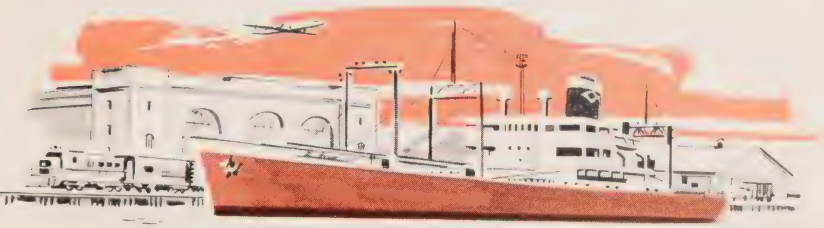
4. BUREAU OF SCIENTIFIC ADVISORY SERVICES

The Bureau of Scientific Advisory Services provides the Directorate with investigative, consultative and advisory services (a) in the evaluation of submissions of technical data and information required under the Food and Drugs Act in connection with all new drugs, investigational new drugs, food additives and pesticides, (b) with regard to cosmetics and medical devices and (c) with regard to standards established in the regulations under the Act.

This work involves a wide variety of scientific disciplines including medicine, veterinary, pharmacy, pharmacology, endocrinology, food technology, biochemistry, etc. For purposes of administration, the bureau is made up of four main divisions — Medicine, Veterinary Medicine, Pharmacological Evaluation, and Standards and Additives. Each of these divisions embraces a number of sections, staffed by specialists in fields related to the division's activities.

5. NARCOTIC AND CONTROLLED DRUG DIVISION

The responsibility of the Narcotic and Controlled Drug Division is to see that firms or persons who import, manufacture, distribute and sell narcotics and controlled drugs adhere to the requirements of the Narcotic Control Act and the Controlled Drug Regulations of the Food and Drugs Act. Under this legislation, importers, manufacturers and distributors of narcotics and controlled drugs must be licensed and are known as "Licensed Dealers". Every Licensed Dealer is required to keep complete records, with dates, showing the quantities and names of drugs received by him or supplied by him and the names and addresses of the suppliers or recipients.



These records must also show: (a) the quantities manufactured; (b) the quantities used in the manufacture of other drugs and (c) the quantities on hand at the end of each month. Such records are checked and verified and periodic inspections are carried out by Auditor-Inspectors to ensure that proper records are maintained at all times.

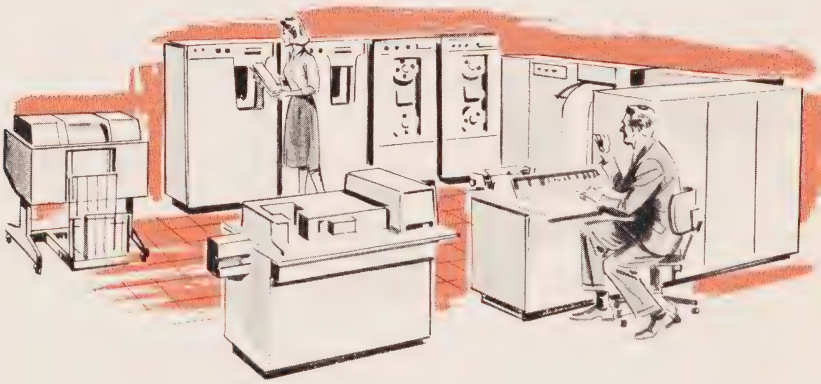
The division also keeps records of doctors prescribing these types of medication and of known addicts and deals with cases of abuse.

6. ADMINISTRATIVE SERVICES

Administrative procedures are developed by the Administrative Services Division which also supplies all support

services required by the directorate. These include accommodation planning and maintenance, office services of every type, records, workshop and many others.

When officers of the directorate wish to lay their hands quickly on a particular document or other piece of information, they turn to the Scientific Information Retrieval Centre. This unit of Administrative Services exists for the collection and rapid retrieval of all rulings and decisions of the directorate and of related background information. Scientific information and information on the various components and properties of drugs, foods, food additives, cosmetics and pesticides are also collected, and the unit will, on request, search literature for research projects. The centre was organized in 1962 using a manual "keyword" system of indexing. Mechanization is being introduced gradually with the eventual goal of microfilm records, possibly coupled with a computer system.



IV.

DRUG ADVISORY COMMITTEE

A Drug Advisory Committee, established by the Minister of National Health and Welfare, advises the Food and Drug Directorate on matters pertaining to drugs.

This committee meets at least once a year to discuss proposed regulations or policies in administering the laws as they apply to the sale of drugs. Its membership consists of representatives of the Canadian Medical Association, the Royal College of Physicians and Surgeons, the Canadian Pharmaceutical Association, the Canadian Pharmaceutical Manufacturers' Association, the Proprietary Association, the Pharmacological Society and representatives of the directorate.

A subcommittee advises on the necessity of placing drugs on "Schedule F" to the Food and Drug Regulations, thus restricting their sale to doctors' prescription only. "Ad hoc" committees, to advise on problems related to drugs in which expert knowledge in depth of a particular field is needed, are appointed as necessary.

V.

LABELLING

Read The Label — It's Your Protection

Labels are required to display, clearly and prominently, information for the consumers' protection. The information may prevent such economic fraud as the labelling of a cheaper or inferior product as that of a superior one. Labels may prevent possible injury to health by display of "warning" statements on food and drugs. In the case of drugs, adequate directions for use, including the proper doses, are carried on the labels.

1. FOODS

Certain important information must appear on the main panel of the label, i.e., the portion or surface one would normally expect to see facing one on the grocery shelf. Included in this requirement are:

- *The brand or trade name, if any*

- *The common name, i.e., the name by which the product is commonly recognized. For many foods the common name is laid down in the regulations.*

- *A net declaration of contents for all packages weighing more than two ounces gross. This may be stated in terms of weight, measure or number, according to usual practice for the article in question, and it must be placed in close proximity to the common name.*

Most other required information, with the exception of the name and address of the manufacturer, must be grouped together, either on the main panel or on any panel other than the bottom. This includes:

- *For foods consisting of more than one ingredient, a complete list of ingredients by their common names, in descending order of proportion or by percentage. However, foods for which a standard is laid down in the regulations do not normally require a list of ingredients.*

- *A declaration of any preservative used, with the exception of the more familiar ones such as salt, sugar, dextrose, spices, vinegar, wood smoke, etc., referred to in the regulations as "Class I" preservatives.*

- *A declaration of any added food colour.*

- *A declaration of any artificial or imitation flavouring preparation.*

- *In the case of dietetic foods, a statement of the type of diet for which the product is recommended and such necessary and informative announcements as declarations of calories, carbohydrates and sodium content per 100 grams.*

- *The name and address of the manufacturer must appear: it may be placed on any panel except the bottom of the package, but need not be grouped with required information.*

2. DRUGS

Most packaged drugs have both an inner and outer label. Some of the information required by the Food and Drug Regulations must appear on both labels, while some need appear on the outer label only.

Inner and Outer Label

The following information must appear on the MAIN PANEL of both the inner and outer labels:

- *The proper (non proprietary or generic) name of the drug. If there is no proper name, the common name. Where a proprietary or brand name is used, the proper name must immediately precede or follow it, in type of not less than one-half the size of the proprietary or brand name.*
- *In the case of standard drugs, the standard under which the drug was manufactured; or, where applicable, the Canadian License number.*

Also required to appear on both inner and outer label, but not necessarily on the main panel, are:

- *The name of the manufacturer or distributor of the drug.*

- *The address of the manufacturer or distributor, except that where the immediate container holds five millilitres or less, this statement need not be made on the inner label.*
- *Where a drug is intended for internal or parenteral use, the lot number.*
- *Adequate directions for use.*
- *A quantitative list of the medicinal ingredients contained therein by their proper names or, if they have no proper names, by their common names, except upon:*
  (a) Shipping cases or wrapping material;
  (b) Official drugs;
  (c) Drugs sold on prescription;
  (d) Medicines registered under the Proprietary or Patent Medicine Act.
- *The statements "Investigational Drug" and "To be Used By Qualified Investigators Only" on new drugs which have not yet been released for general use but which may be used by qualified investigators for the sole purpose of obtaining clinical and scientific data with respect to the safety, stability, dosage or efficacy of the drug.*

Outer Label Only

Information which is required to appear on the outer label only includes:

- *A correct statement of net contents in terms of weight, measure or number.*
- *The name and proportion of any preservative present in a drug intended for parenteral use.*

Labelling requirements may vary. For instance, the labels of sex hormones, antibiotics and Canadian Standard Drugs may require some or all of the following additional information: lot numbers, potency and the expiration date after which the drug should not be used.

Under certain conditions, special cautions and statements such as "For Therapeutic Use Only", "For Use by Qualified Investigators Only" or "For Veterinary Use Only" must be added to the labels.

If a package of a drug has only one label, then that label must contain all the information required by the regulations to be shown on both the inner and outer labels.

3. VITAMINS

Preparations which may be labelled, advertised or sold as vitamins in Canada are restricted to those specified in the Food and Drug Regulations.

Special information is required on the labels of drugs represented as containing vitamins and foods to which vitamins have been added. For example, the amount of the vitamin present must be stated in specified units, as outlined in the regulations. The lot number must be shown on vitamin preparations intended for internal or parenteral use. There must be adequate directions for use of drugs represented as containing a vitamin. An expiration date must appear, consisting of the words "expiry date" or "expiration date" followed by the name of the month and the year indicating the period during which the drug will maintain its labelled potency. This period must be determined by the manufacturer who will be required to show, on request, that the product conforms to the labelled potency during the period indicated on the label. Drugs containing vitamins which furnish in the largest recommended daily intake more than the amounts prescribed in the Food and Drug Regulations must be labelled, "NOTE: For Therapeutic Use Only".

Foods to which no vitamins have been added but which contain minimum specified amounts of vitamins may be labelled as "a good source" or "an excellent source" of a vitamin, depending on the amount of vitamin *naturally* present. Labels of foods to which a vitamin has been added must carry a statement of the amounts of each of the vitamins present and may *not* be referred to as a good or excellent source of the vitamin.

4. COSMETICS

The label must carry:

- *The name of the cosmetic and, in some cases, a description.*
- *The name and address of the manufacturer or distributor.*
- *A declaration of net contents, except for perfume and toilet water whose net content is four fluid ounces or less, and solid or liquid cosmetics whose net content is one ounce or less.*
- *If a hazard exists, directions for safe use and, in some cases, a warning statement.*
- *For cosmetics containing sex hormones, a declaration by its proper name of the sex hormone present, together with a statement of its potency. Cosmetics containing sex hormones may not be sold unless they are free from systemic effect from the sex hormone.*

REMEMBER . . . ALWAYS READ THE LABEL!

VI.

THE CONSUMER'S PART

Every individual has a part to play in the matter of consumer protection, and this is especially true concerning foods, drugs and cosmetics. While it is true that it is the job of the Food and Drug Directorate to minimize health hazards and fraud or deception in these fields, there are many things that consumers can do for themselves and thus avoid further restrictions by law. The fact must be faced that requirements enforced on the manufacture, labelling, advertising and sale of foods and drugs are not likely to provide cheaper products. "Leaving *everything* to the government" can be costly!

Honest mistakes are sometimes made by even the most conscientious manufacturers. In the majority of cases they are grateful when this is drawn to their attention by a consumer and are quick to make redress. There are times therefore when consumers should write manufacturers and make their grievances known. However, the consumer is encouraged to report to the directorate all evidence of

irresponsible, fraudulent and unsanitary or otherwise dangerous practices.

Consumers should take the time to read labels. Under Food and Drug requirements, labels are more than an embellishment or eye-catcher. They must contain certain items of important information, as pointed out elsewhere in this booklet, and, in the case of drugs, and cosmetics, often contain vital directions for use and cautions or warnings. Too often consumers ignore this information and have cause to reget it.

How to Report a Complaint

If you have a complaint to report about any food, drug, cosmetic or medical device, write to

Consumer Division
Food and Drug Directorate
Department of National Health and Welfare
Tunney's Pasture
Ottawa 3, Ontario

or get in touch with your nearest food and drug office. Be as explicit as you can and give full details in your first letter or phone call. As a rule, investigation of a complaint traces a backward route. Therefore, it is important to tell your Food and Drug officers not only what the product is, but where and when it was purchased. The retailer can then, if necessary, supply information about the wholesaler, in case that is where the trouble originated. The brand name and the manufacturer's name and address should also be supplied and the code or lot identification if there is one. This may consist of a series of numbers, or letters, or a combination of both. On tins it is usually stamped in the end metal; on glass containers, it often appears on the back of the label and on paper containers it sometimes is found on an end flap. The code number helps to pinpoint any trouble at the manufacturing level for it identifies the product as, for instance, being from a particular batch made on a particular day.

Given the foregoing information, the Food and Drug Inspector can now proceed to the retail store named by the consumer and try to obtain further samples of the same lot of the product. These are then examined and, if the condition complained of is confirmed in any of these samples, the trouble is traced to its source and corrective action taken. This may range from a warning to the seizure of a whole line of goods and even their destruction if the fault cannot be remedied. Where gross carelessness or willful evasion of Food and Drug laws exists severe penalties may follow.

If a number of samples are examined and found faultless, the complaint may be termed an isolated one, and, depending on the nature of the trouble, outside of advising the complainant further action may not be necessary.

VII.
HELP FOR THE CONSUMER

When problems arise or help is needed, Food and Drug officers are glad of the opportunity to extend a helping hand. Write to the Consumer Division at Ottawa *(see* address on page 33) or get in touch with one of the thirty or so Food and Drug offices distributed across Canada. If there is one in your city, you will find it listed in your telephone directory — or you may call the federal government operator.